By way of example only, all of the inflation ports may be located in the middle of the balloon and inflatable members.

[0063] The inflation fluid may be in the form of a gas or a liquid and may be at room temperature, cooled or heated. Optionally, a controller may be provided to control the temperature of the inflation fluid. Where the inflatable member is made of a material characterized by a glass temperature $T_g$ or a crystallization temperature $T_c$, the inflation fluid may suitably be heated, but the temperature should remain below that of the $T_g$ or $T_c$ of the inflatable member to prevent deformation. Typically, in cases where the inflation fluid for the inflatable members is heated, the fluid will be heated to a temperature in excess of the temperature of the balloon which is being configured so that the inflatable members are warmer than the balloon. When the warmed inflatable members contact the balloon, the balloon is warmed and preferentially softened in the region of the inflatable members as compared with the remainder of the balloon thus facilitating configuring of the desired region of the balloon. The balloon may also be at least partially inflated with an inflation fluid which is cooler than the inflation fluid delivered to the inflatable members in order to preserve any internal structure in the balloon.

[0064] A controller may also be used to control the pressure of the inflation fluid, the rate of increase and/or decrease of the pressure of the inflation fluid as well as the period of time in which the pressure is maintained. The period of time in which the pressure is maintained will depend on a variety of factors including the pressure of the inflation fluid and the relative temperatures of the inflatable members and the balloon.

[0065] Device 100 may further comprise a housing 128 in which inflatable members 116 are constrained. Typically, the housing will be in the form of a rigid tube which may be made of any suitable material which is capable of constraining the inflatable member including metal, glass, rubber or plastic. Desirably, housing 128 will be made of a clear material to allow for monitoring of the balloon as it is configured.

[0066] In one embodiment of the invention, as shown in Figs. 1, 6 and 7, device 100 may further comprise first end support 131 including first end cap 132 and second end support 135 including second end cap 136. In the illustrated embodiment, first end cap 132 is disposed at a first end of housing 128, second end cap 136 is disposed at a second end of housing 128 and inflatable members 116 extend between the first and

second end caps. Optionally, the first and second end caps may support the inflatable members and serve to align the inflatable members. As shown in Fig. 1, one or more optional connecting members 137, in the form of bolts, join the first and second end supports. Other types of connecting members may also be used if desired. For example, the body portion of the device including the first and second end supports may be of one piece construction (not shown) or may be joined by a base member (not shown). The device may also be provided without any additional connectors between the first and second end supports. The end supports may also be adhesively joined or otherwise joined to the rigid tube or may be integrally formed with the rigid tube.

[0067] At least one of the end caps, desirably, first end cap 132, has an opening 148 therethrough sized to receive the balloon portion of the balloon catheter therethrough. As shown in Fig. 6, opening 148 is configured to allow removal of a winged balloon therethrough. Opening 148 is shown having three portions 148a-c corresponding to the winged portion of a balloon. Opening 148 may be provided with additional portions to accommodate in excess of three balloon folds or with fewer portions. Opening 148 can assume any other shape which would allow for removal of a balloon from the apparatus.

[0068] Desirably, second end cap 136 also includes a recess or an opening 150 therethrough for supporting a portion of the balloon catheter in a region adjacent balloon contacting portion 124 of inflatable member 116. In embodiments without a second end cap, an optional opening for supporting a portion of the balloon catheter may be provided directly in the second end support.

[0069] In the embodiment of Figs. 1-3, 6 and 7, three inflatable members 116 are provided, each with a balloon contacting portion. Typically, at least three to twelve or more balloon contacting portions will be provided. As few as a single balloon contacting portion may be provided where it is desired to place a single pleat in a balloon.

[0070] Balloon contacting portions are desirably spaced about the circumference of a circle. More desirably, the balloon contacting portions are spaced regularly about the circumference of the circle.

[0071] It is further within the scope of the invention to provide a device comprising a plurality of segments each of which comprises inflatable members. Such a device is capable of providing more complicated pleats in a balloon. An example of such a device

comprising two segment of inflatable members 116a and 116b is shown in longitudinal cross-section at 100 in Fig. 10. Each half of balloon 104 may be configured independently of the other half. In one embodiment, the device of Fig. 10 may be used to gradually configure a balloon by initially configuring half of the balloon using inflatable members 116a and subsequently configuring the other half of the balloon using inflatable members 116b. Using this embodiment, the first and second segments of the device may differently configure each end of the balloon.

[0072] In yet another embodiment of the invention, shown generally at 100 in Fig. 11a, a plurality of inflatable members including members 116a-f are disposed spirally along the length of balloon 104. Upon inflation of inflatable members 116, a plurality of spiral pleats 104a and 104 b are placed in balloon 104, as shown in Fig. 11b.

[0073] Other arrangements of inflatable members which are capable of providing more complex shaped pleats are within the scope of the invention as well. Circumferential pleats, for example, may be formed by providing a device with a plurality of donut shaped inflatable members about the balloon and inflating the inflatable members.

[0074] In use, as shown in Fig. 12, balloon portion 104 of catheter 108 is inserted in channel 120 between inflatable members 116. Balloon portion 104 is at least partially inflated. In the view of Fig. 12, optional first and second end supports are not present. An inflation fluid is supplied to inflatable members 116 to expand inflatable members 116 inward, as shown in Fig. 13 and in transverse cross-section in Fig. 14. As inflatable members 116 expand inward, they apply an inward force to those portions of balloon 104 that they contact. When inflation of inflatable members 116 is complete, balloon 104 includes a plurality of winged portions 104a-c. Balloon 104 may then be removed from device 100.

[0075] The invention is also directed to a device such as that shown generally at 100 in Figs. 15-19 for configuring an inflatable balloon of a balloon catheter assembly. Device 100 comprises a body 112 with first end support 131 and second end support 135 and a housing 128 extending therebetween. Typically, housing 128 is in the form of a rigid tube. One or more inflatable members 116 having a balloon contacting portion 124 are disposed in housing 128. In the embodiment of Figs. 15-18, a single inflatable member 116 is provided. Adjacent balloon contacting portions are separated by constraining members 152, desirably in the form of slats between balloon contacting portions 124. On expansion of inflatable member 116, only balloon contacting portions 124 are free to